IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant

WR'T, Jeffrey L.C.

Appln. No.

09/385,834

Filed:

August 30, 1999

Title

A Nutritional Supplement for Lowering Serum

Triglyceride and Cholesterol Levels

Grp./A.U.

1616

Examiner

QAZI, Sabiha Naim

Docket No.

76891

## DECLARATION PURSUANT TO 37 CFR § 1.131

I, JEFFREY L. C. WRIGHT, hereby declare that:

- 1. I am the inventor of the pending claims of the above-identified patent application.
- 2. Prior to December 15, 1998, I conceived the idea of using a sterol ester of an omega-3 fatty acid as a nutritional supplement for lowering both cholesterol and triglyceride levels in the bloodstream of a subject. Attached hereto as Exhibit A is a redacted copy of a letter from me to my original patent agents, explaining our idea of esterifying fish oil omega-3 fatty acids with natural sterols to create a bifunctional nutraceutical product which will lower cholesterol and triglyceride levels. The date of the letter deleted from Exhibit A is prior to December 15, 1998. Information not relevant to conception of my invention has also been deleted.
- 3. My original patent agent, Mr. Omar Nassif, sent me a preliminary draft of the patent application under cover of a letter dated April 12, 1999.
- 4. Subsequent to the preparation of the first draft of the application we engaged another firm to revise and complete the application. On June 14, 1999, I met with Joy Morrow and Ian Clark of the firm of Smart & Biggar to discuss the invention and the draft application.
- 5. My colleague H. Stephen Ewart, who was conducting animal studies concerning the nutritional compositions of the invention, sent additional materials to Mrs. Morrow by way of a letter dated June 17, 1999.

- 6. In connection with preparing a second draft of the patent application, Mrs. Morrow posed to us further questions in a letter dated June 24, 1999 addressed to my colleague Stephen Ewart.
- 7. Dr. Ewart responded to Mrs. Morrow's further questions in a letter to Mrs. Morrow dated July 5, 1999.
- 8. Mrs. Morrow sent us a second draft of the patent application under cover of a letter dated August 13, 1999.
- 9. Stephen Ewart and I discussed the revised draft of the patent application with Ian Clark of the Smart & Biggar firm on August 16, 1999.
- 10. Mr. Clark sent us a third draft of the patent application as an attachment to an e-mail message dated August 18, 1999.
- 11. I discussed this further draft of the patent application with Mr. Clark some time between August 18 and August 23, 1999 and on August 23, 1999, Mr. Clark sent me a further e-mail message with a final draft of the application for review.
- 12. I understand that the finalized application was subsequently filed at the USPTO on August 30, 1999.
- 13. I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

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effrey L. C. Wright

16th April 2003

Date



TECH CENTER TOOOS

This is Exhibit A to the Declaration of JEFFREY L. C. WRIGHT



Mr. Omar Nassif
Gowling, Strathy and Henderson
Commerce Court West
Suite 4900
Toronto, ON MAL 1J3

Dear Mr. Nassif:

Please find enclosed a draft of our patent proposal concerning a new class of nutraceuticals that we call bifunctional nutraceuticals. Both components of a bifunctional nutraceuticals must display a biological effect. One component is not there merely as a carrier or solubilizer, it is included with a specific purpose of positively modulating a health condition or state.

In this case we wish to patent a bifunctional nutraceutical that will simultaneously lower serum triglycerides and cholesterol levels - two key risk factors of cardiovascular disease.

Our proposal then is to esterify markedly different in biological properties) with natural sterols thus creating our bifunctional nutraceutical product which will lower cholesterol and triglycerides. That is the crux of our patent.

I would very much appreciate your evaluation of this patent application, and if your assessment is positive I would like you to indicate what the next steps are and what needs to be done to obtain a U. S. Patent (and likely others if that is your recommendation) as quickly as possible.

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As I mentioned to you on the phone we have all the reprints referenced in the patent application on hand and we can supply you with an entire paper or abstract as necessary.

Thank you for your attention. I look forward to hearing from you.

Yours sincerely,

Jeffrey L. C. Wright C. M., Ph. D., FCIC

Executive Director of Research Ocean Nutrition Canada Ltd.